DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
M22391

San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94102-7070
Telephone: 510-337-6700

Via Federal Express

Our Reference 29-51354

December 10, 1998

Manuel Carmo
Carmo Dairy
10775 Franklin Boulevard
Elk Grove, California 95624

WARNING LETTER

Dear Mr. Carmo:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your firm on December 3, 1998, by Food and Drug Administration (FDA) Investigator Karen L. Robles has revealed serious violations of the Federal Food, Drug, and Cosmetic Act as follows:

A food is adulterated under Section 402(a)(2)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512. On September 15, 1998, you sold a cow (identified by USDA laboratory report number 283322) for slaughter as human food. This cow was delivered for introduction into interstate commerce by your firm and was adulterated by the presence of illegal drug residues. USDA analysis of tissues from this cow revealed penicillin in the kidney at 0.43 parts per million (ppm) and in the liver at 0.06 ppm. Presently, the tolerance level for penicillin is 0.05 ppm in the uncooked edible tissues of cattle.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so inadequate that medicated animals bearing possibly harmful drug residues are likely to enter the food supply. For example, our investigator noted the following:

1. You lack an adequate system for determining the medication status of animals you offer for slaughter.

2. You lack an adequate system for assuring that animals to which you administer medication have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs.

3. You lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in their labeling.

4. You lack an adequate inventory system for determining the quantities of drugs used to medicate your cattle.

You are adulterating the drug Penicillin G Procaine within the meaning of Section 501(a)(5) of the Act in that it is a new animal drug within the meaning of Section 201(v) and unsafe within the meaning of Section 512(a)(1)(B) of the Act since it is not being used in conformance with its approved labeling. Labeling for penicillin prescribes a dosage of 1 milliliter (ml) per 100 pounds of body weight and warns against using more than 10 ml into one site. The label also requires a ten day withholding time prior to slaughter. Your practice of administering 25 ml of penicillin per day in two sites of a 1200 to 1500 pound animal results in a dosage in excess of that allowed by the labeling. Overdosing cattle with penicillin, coupled with an inadequate withdrawal period, presents a possibility that illegal residues will occur and is likely the cause of the illegal residues found in the cowl you sold for food use. Failure to comply with the label instructions on a drug presents the likely possibility that illegal residues will occur and makes the drug unsafe for use.

We request that you take prompt action to ensure that animals which you offer for sale as human food will not be adulterated with drugs or contain illegal residues.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act.

Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal for sale to a slaughter facility where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

Your firm has established a history of offering cull cows and calves for sale for human food use which have been found to be adulterated due to the presence of drug residues. According to USDA analytical reports, during the period of June 10, 1993, through May 1, 1996, your firm offered two cows and three calves for food use which were found to contain illegal drug residues. During this same period you delivered two calves which were found to be CAST positive due to the possible presence of harmful levels of antibiotics. An inspection of your dairy was conducted on July 21, 1994. During the inspection you were warned that it is illegal to market animals with illegal levels of antibiotics. A Warning Letter, dated August 19, 1994, was sent to you as a result of the violations found during the inspection. Also, the USDA sent you a letter for each instance in which their analysis found violative levels of drug residues. You have failed to take corrective action. It is your responsibility to ensure that all requirements of the Act and regulations are being met. Failure to achieve prompt corrective action may result in enforcement action without further notice, including seizure and/or injunction.

Within fifteen (15) days of the receipt of this letter, notify our Sacramento resident post office in writing of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the inspection and in this letter, and should include copies of any documentation demonstrating that corrections have been made. Please direct your reply to Karen L. Robles, Investigator, U.S. Food and Drug Administration, 801 I Street Room 443, Sacramento, California 95814.

Sincerely yours,

for Patricia Ziobro
District Director
San Francisco District

cc: [redacted]